DETAILED ACTION

Response to Arguments

Applicant's arguments filed 7-2-10 have been fully considered but they are not persuasive.

With respect to **Allen**, Examiner agrees the amendments to claim 1 overcome the previous rejection.

With respect to **Finger**, Examiner agrees the amendments to claim 20 overcome the previous rejection.

With respect to **Hicks**, Applicant argues that **Hicks lack tunnels and chimneys** as claimed because there are no preformed suture passages. Examiner disagrees because Hicks disclose the device is sutured, and thus the resulting structure includes tunnels as claimed (which could have a suture removed and a new suture placed therein).

Claim Objections

Claims 1 and 31 are objected to because of the following informalities: "the elongation toward the medial side" does not clearly describe the direction of the elongation and Examiner suggests using language as recited in claim 29. Claim 31 recites elevated *protrusion* (line 10). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase "the implant having a quasi-spherical shape defined by not more than one conical elongation, the elongation toward the medial side of the posterior side" is not supported by the original disclosure. For example, mounds on the anterior side may be considered conical and attributing to the quasi spherical shape.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3,4,12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 requires not more than one elongation, but claims 3,4, and 12 add additional elongation structures.

Drawings

Figure 13 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled

"Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hicks et al. USPN 6346121.

Hicks et al. disclose acrylic orbital implants comprising two pieces joined together and having tunnels and chimneys capable of tissue ingrowth and passage of sutures. See figures 2,5, c3:57-c5:4, and Examples 1,3, and 5. Furthermore, the tunnels may be considered formed during implantation as the device is sutured in place.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8,12-14, 20, 26,28,29, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen 3070808, as applied above, and in further view of Kelman USPN 4370760, Hicks et al. USPN 6346121, Rubin USPN 5466258, Jardon USPN 2571721, and Grip USPUB 20040039445.

Allen disclose in figures 1-4 an orbital implant formed of one-piece acrylic and having a quasi-spherical shape and astigmatic features as claimed (see figures 2-3). The plurality of openings (as broadly claimed) are described at c3:28-55 and may have sutures/needles passed therethrough, and may extend from the anterior region to the posterior region (figure 3). Anterior valleys and mounds (astigmatism) for keying with a prosthetic eye are provided, and a visible marking are shown in figure 1.

Regarding claims 1,2,29, Allen is silent as to providing a quasi-spherical shape defined by a posterior elongation toward the medial side. **Rubin** teach orbital implants comprising a conical posterior elongation (see Figures 1,4-9, c3:24-28). Furthermore, Rubin teach the implant need not be symmetric about the vertical central plane and, for example, the lateral side could be truncated which would result in an overall elongation toward the medial side of the posterior end in order to properly fit a patient. Alternately, an asymmetric shape would reasonably teach an implant with an elongation to one side which could be termed the medial side. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant of Allen to include a medial elongation in the posterior region as taught in Rubin in order to provide an enhanced fit to a patients orbit. Furthermore, it is well known in the art to provide custom shapes to fit particular patients by modifying the shape of a projection, and that

the posterior region typically requires further material to fill the orbit as evidenced by **Grip** USPUB 20040039445.

Regarding claims 7-8,20,26,28-29, and 31 Allen lack the express written disclosure of using two separate parts (claims 20,31), openings extending through two separate parts (claim 7), joining two parts by ultrasonic welding (claims 8, 28), and wherein the parts comprise a key to ensure alignment (claim 31).

Each of **Kelman** and **Hicks** teach ocular implants which may comprise unitary construction or separately constructed parts joined together. Kelman further teach the well-known use of ultrasonic welding. See Hicks c3:61-67 and Kelman c5:45-52. Furthermore, modifying a component into separately formed parts to be subsequently joined has been held to be within the realm of obvious design choice (*In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348,349 (CCPA 1961)). Also see MPEP 2144.04(V)(C). Still further, Hicks provide motivation to separate the parts in order to provide different properties along the device, and one of ordinary skill in the art would further realize a possible improvement in the manufacturing process in order to create the uniquely shaped structure of Allen including tunnels and chimneys whereby the tunnels or openings are split amongst two parts that are joined (for example, if the device were divided in the top to bottom direction as shown in Figure 3 of Allen).

With respect to the key limitations of claim 31, Allen is silent as to a key mechanism between the portions of part 12 but does teach a key system for attaching two orbital implant parts (12 and 13). Furthermore, **Jardon** teach a key (Figures 8-9) for ocular implants requiring alignment in order to allow the parts to be joined.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Allen by forming the device into separate parts, as taught by Kelman and/or Hicks, in order to provide different properties along the length of the device or to improve the manufacturing process, and to further to join the parts by ultrasonic welding, as taught by Kelman, in order to securely join the parts, and to provide alignment key structures as taught in Jardon or Allen in order to provide a key structure to properly align the components. Such modifications amount to substitution of known manufacturing techniques and are well within the technical capabilities of one of ordinary skill in the art.

Regarding claims 14 and 32, Allen does not show at least 14 openings or disclose the openings for sutures to be 1-2 mm in diameter, however Allen teaches various sets of openings at c3:28-55, which may be used for suturing, and specifically teach that even more passages may be used to enhance support of the implant. It would have been obvious to provide more than 14 openings as taught in Allen in order to provide enhanced fixation of the implant in the socket, and further to provide the openings with a diameter of 1-2mm in order to easily allow a suture needle to pass therethrough.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen as modified supra, and further in view of Finger USPN 6419698.

Allen, as modified supra, meet the limitations of claim 27 as described above but lack the express written disclosure of using silicone material. Finger teaches ocular

implant devices comprising silicone due to its biocompatibility. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the orbital implant disclosed by Allen to include silicone as taught by Finger in order to utilize known biocompatible materials.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/

Primary Examiner
Art Unit 3774